UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

NOVO NORDISK INC. and NOVO NORDISK PHARMA, INC., Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, Defendants.	Case No. 3:23-cv-20814-ZNQ

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION

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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers that wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs (VA) do so at statutorily defined ceiling prices, and both agencies have authority to negotiate prices further below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). Building on this model in the Inflation Reduction Act of 2022 (IRA), Pub. L. No. 117-169, Congress granted the Secretary of Health and Human Services similar authority to negotiate how much Medicare will pay for pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. *See* 42 U.S.C. § 1320f(a) (establishing the "Negotiation Program"); *id.* § 1320f-1(b), (d), (e) (specifying which drugs are eligible for negotiation). For the first time, Medicare will be able to decide how much it is willing to pay for certain prescription drugs it covers—just as it has long determined how much it will reimburse doctors, hospitals, and other providers for medical services provided to Medicare beneficiaries.

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare's prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. And now that their lobbying failed, pharmaceutical companies and interest groups have repacked their policy disagreements into lawsuits, filing complaints around the country challenging the statute on its face. This lawsuit, brought by Plaintiffs Novo Nordisk, Inc. and Novo Nordisk Pharma, Inc. (Novo), largely rehashes the same legal theories proffered by the other manufacturers. And it fails for the same reasons.

As a threshold matter, this Court lacks jurisdiction to review Novo's statutory claims (Counts III and IV of Novo's complaint). In enacting the IRA, Congress expressly stated that that there "shall be no administrative or judicial review" of certain administrative actions that CMS takes in the course of implementing the Negotiation Program. 42 U.S.C. § 1320f-7. Key among these is CMS's "selection of drugs" for negotiation under 42 U.S.C. § 1320f-1 and certain specified precursor determinations, including what constitutes a "qualifying single source drug." 42 U.S.C. § 1320f-7(2). Yet Novo's summary-judgment brief makes clear that it is contesting the very determinations Congress made unreviewable. *See* Pls. Sum. J. Br., ECF 28-1 at 1-2 (Pls. Br.). Its ultra vires arguments challenge CMS's authority to determine—and prescribe methodologies concerning—what "grouping of products" are sufficiently similar to be considered a single "drug" eligible for negotiation. *Id.* at 2 (emphasis removed). Both the plain text of the IRA and case law analyzing similar bars to judicial review in other parts of the Medicare statute confirm that this Court cannot entertain those challenges, no matter how framed.

In any event, even if this Court had jurisdiction to consider them, Novo's statutory claims are meritless. The guidance that CMS issued to advise manufacturers and the public about how it intends to implement the first cycle of the Negotiation Program explains in detail why biological products like Novo's that share the same "active ingredient" constitute a single negotiation-eligible drug under the IRA. Contrary to what Novo argues, CMS's approach is consistent with the plain language and structure of the IRA—and Congress expressly authorized CMS to announce this kind of approach through guidance. Novo's statutory challenges ultimately come down to a disagreement

about policy choices made by *Congress* when it enacted the IRA—but that kind of disagreement does not entitle Novo to relief.

Disposing of Novo's statutory claims leaves Novo's assertions that the Negotiation Program violates the First and Fifth Amendments, as well as the nondelegation doctrine. The first two of those claims fail for the reasons recently articulated by another district court when considering an analogous Due Process Clause challenge to the statute. As that court explained, Congress's authorization for the Secretary to negotiate how much Medicare will pay for drugs "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to participate in the [Negotiation] Program—or in Medicare generally." *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber*). "[P]harmaceutical manufacturers who do not wish to" make their drugs available at negotiated prices can "opt out" by, for example, withdrawing from the Medicare and Medicaid programs or by divesting their interests in the drugs subject to negotiation before 2026, when any negotiated prices would first take effect. *Id.* The Negotiation Program—like Medicare more broadly—is thus "a completely voluntary" undertaking. *Id.* This basic fact defeats Novo's First and Fifth Amendment challenges. Although Novo may be dissatisfied with the conditions Congress imposed on future Medicare spending, Novo is neither deprived of a protected property interest in violation of the Due Process Clause, nor required to speak.

Novo's First and Fifth Amendment arguments fail in other respects, too. Its assertion that the Negotiation Program violates due process fails to identify any protected property interest that Congress ostensibly impaired. As courts have made clear,

parties have no protected property interest in their Medicare reimbursement rates—so Congress's alteration of the manner in which such rates are established cannot contravene the Fifth Amendment. Likewise, contrary to Novo's assertions, neither the agreements that manufacturers have now signed with the Centers for Medicare & Medicaid Services (CMS), nor any other component of the Negotiation Program, requires a manufacturer to adopt the government's message. Indeed, those agreements do not require manufacturers to express any views at all. Those instruments are purely commercial arrangements that pertain solely to the manufacturers' conduct. Novo's unfounded fears about how those agreements might be perceived by the public do not justify abrogating decades of First Amendment case law in favor of a new—and limitless—presumption of First Amendment expression in every commercial act.

Finally, Novo's request that the Court strike down the IRA as an excessive delegation of legislative power fails to overcome ninety years of precedent. The IRA is far more detailed than many of the statutory schemes that the Supreme Court has sustained against nondelegation challenges. Novo offers no principled reason to depart from those precedents.

In creating the Negotiation Program, Congress exercised its constitutional prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const., art. I, § 8, cl. 1. Novo's objections to that program are nothing more than "a dispute with the policy choices" made by Congress masquerading as constitutional theory. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.* Novo is not entitled to relief in court.

BACKGROUND

I. MEDICARE AND THE IRA'S DRUG NEGOTIATION PROGRAM

A. Medicare is a federal program that pays for covered healthcare items and services, including prescription drugs, for qualified beneficiaries. *See generally* 42 U.S.C. § 1395 *et seq.* The Medicare statute encompasses several "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (citation omitted). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* Prior to the IRA, Congress had not granted the Secretary authority to directly negotiate with drug manufacturers for the costs of covered medications under Medicare. To the contrary, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

Although this model was relatively economical at first, it has contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled

over the last decade, and as of 2019 it was "projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Office, *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* at 36 (May 2021), https://perma.cc/9L42-VRBK.

For example, manufacturers of brand-name drugs often fend off generic competitors by introducing inconsequential changes to their drug and shifting patients to that new version, a strategy known as "product hopping." H.R. Rep. No. 116-695, at 3 (2020). Similarly, brand-name manufacturers often protect their market share by entering into "settlements" with generic manufacturers that permit the generic to be marketed only nominally, without resulting in meaningful competition. *See, e.g.*, Sarah M.E. Gabriele, et al., *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 2023 JAMA 1223 (2023). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* at 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, undermining

the program's premise of using market competition to reduce prices for beneficiaries and costs for taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under Part D, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Pub. L. No. 117-169, §§ 11001-11003 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. § 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for selected drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of "negotiation-eligible drugs" from a set of "qualifying single source drugs." 42 U.S.C. § 1320f-1(d)-(e) (defining "negotiation-eligible drug" and "qualifying single source drug"). Congress explicitly required CMS to make these determinations by using "data that is aggregated across dosage forms and strengths of the drug." *Id.* § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). Using that data, the agency is then to select up to 10 such drugs for negotiation for initial price applicability year 2026, up to

15 drugs for initial price applicability years 2027 and 2028, and up to 20 drugs for initial price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)-(b).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. In formulating offers during the course of those negotiations, the statute requires CMS to consider numerous categories of information, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) "current unit costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings for the American people, Congress imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS is directed to sign agreements to negotiate prices for selected drugs with willing manufacturers. *Id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to establish the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling the selected drug to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its

own choices about negotiations. *See* Medicare Drug Price Negotiation Program: Revised Guidance at 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from Medicare and Medicaid—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those Congress has long attached to other government healthcare programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs—agreements which give the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). Like those statutory provisions, the Negotiation Program thus gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. CMS'S IMPLEMENTATION OF THE NEGOTIATION PROGRAM

Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, Medicare Drug Price Negotiation Program: Initial Memorandum (Mar. 15, 2023), https://perma.cc/8X4K-CVD8 (Initial Guidance). After considering more than 7,500 public comments "representing a wide range of views,"

CMS published a Revised Guidance on June 30, 2023. Revised Guidance at 1-2. The Revised Guidance applies only to initial price applicability year 2026. *Id.*

The Revised Guidance describes several aspects of CMS's implementation of the first year of the Negotiation Program, including the methodologies by which CMS selects drugs for negotiation, the negotiation process, and the types of data that CMS considers in making an offer. The Revised Guidance also explains how CMS makes the determination of whether a product constitutes a "qualifying single source drug"—that is, a drug that can eventually be found eligible for negotiation and ultimately selected. 42 U.S.C. § 1320f-1(e). As relevant here, the Revised Guidance explains that, consistent with 42 U.S.C. §§ 1320f-1(d)(3)(B) and 1320f-5(a)(2), CMS will consider a qualifying single source drug to include "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."[1] Revised Guidance at 99. Similarly, the Revised Guidance considers a qualifying single source drug for biological products to include "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs." *Id.*[2]

[1] Active moiety is "[t]he molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2411 n.1 (2019) (quoting 21 C.F.R. § 314.3(b) (2018)).

[2] In general, in order to market an innovator drug or biological product in the United States, an applicant must receive FDA approval of an NDA pursuant to 21 U.S.C. § 355(c) or licensure of a BLA pursuant to 42 U.S.C. § 262(a), respectively.

Separately, CMS's Revised Guidance also sets forth the procedures for manufacturers to follow if they decide not to participate in the Negotiation Program. *Id.* at 2-8. In doing so, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33-34. The Revised Guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131-32.

On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The drugs selected accounted for more than $50 billion—or about 20%—of gross Medicare Part D spending between June 2022 and May 2023. *See Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94. The selected drugs included Novo's Novolog, a biological product that uses insulin aspart as its active ingredient. *Id.* Novo markets insulin aspart through several additional brand names, including Fiasp FlexTouch, Fiasp PenFill, Novolog vial, Novolog PenFill, and Novolog FlexPen; consistent with the Revised Guidance, CMS included each of these brand names together as a single selected drug (hereinafter, Novolog). *Id.*

Novo has now executed an agreement to negotiate with CMS. *See Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023),

https://perma.cc/3222-VPEE (*Manufacturer Agreements*). Manufacturers of all the other selected drugs have likewise signed agreements to negotiate the price of their respective drugs. *Id.* Under the schedule established by Congress, negotiations are to conclude by August 1, 2024. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b); *see generally* Revised Guidance at 91-92 (outlining statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026—approximately two years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

III. RELATED LITIGATION

Prior to the deadline to execute negotiation agreements with CMS, drug manufacturers and interest groups filed multiple suits across the country challenging the constitutionality of the Negotiation Program. *See Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Janssen Pharms, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. Aug. 25, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio June 9, 2023). Plaintiffs in one such case—brought by the U.S. Chamber of Commerce and its local affiliates—sought a preliminary injunction "to prevent the implementation of [the] Program." *Chamber,* 2023 WL 6378423, at *1. In doing so, those plaintiffs argued that the Program was akin to utility regulations and would "yield confiscatory rates" in violation of the Fifth Amendment's Due Process Clause. *Id.* at *11. The court disagreed.

As the court detailed, plaintiffs' arguments failed "as a matter of law" because manufacturers were "not legally compelled to participate in the [Negotiation] Program." *Id.* at *11. As a result, the court explained, the Negotiation "Program's eventual 'maximum fair price' cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out[.]" *Id.* (citation omitted). The court thus denied plaintiffs' motion. *Id.* at *14. The *Chamber* plaintiffs did not appeal that decision.

ARGUMENT

I. THE COURT LACKS JURISDICTION TO REVIEW NOVO'S STATUTORY CHALLENGES TO CMS'S DRUG SELECTION

Like other manufacturers that filed suit over the Negotiation Program, Novo claims to be injured by CMS selecting its products for negotiation. Pls. Br. at 14; Compl. ¶¶ 43-46. Unlike most other manufacturers, however, Novo makes a threshold attempt to unwind that selection by arguing that it was ultra vires and contrary to the IRA's terms. *See* Pls. Br. at 1-2; Compl. at 52, 56 (Counts III and IV). But this challenge suffers from a threshold defect. In crafting the Negotiation Program, Congress expressly provided that "[t]here shall be no administrative or judicial review" of CMS's "selection of drugs," as well as specified precursor determinations. 42 U.S.C. § 1320f-7(2) (referring to the selection of drugs under § 1320f-1(b)). And Novo cannot evade that jurisdictional bar.

1. As the Supreme Court has emphasized, "[o]nly Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004) (citing U.S. Const. art. III, § 1). And "what the Congress gives, the Congress

may take away." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017). Given the "'strong presumption that Congress intends judicial review of administrative action,'" courts look for "'clear and convincing evidence' that Congress intended to preclude" a lawsuit. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) and *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967)). This inquiry is made substantially easier, however, when, as here, "Congress provides that 'there shall be no administrative or judicial review' of specified agency actions." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505–06 (D.C. Cir. 2019) (quoting *Knapp Med. Ctr.*, 875 F.3d at 1128). Then Congress's "intent to bar review is clear," and the only relevant question is "whether the challenged action falls 'within the preclusive scope' of the statute." *Id.*

That question is readily answered here. Novo's complaint and summary judgment brief make clear that its statutory claims contest CMS's decision to "subject . . . 6 different Novo products[] to price controls," Pls. Br. at 16—*i.e.*, to "select[]" those drugs for negotiation. 42 U.S.C. § 1320f-7(2). As an outgrowth of those claims, Novo requests vacatur of the selected drug list that CMS published as well as an order prohibiting CMS from acting upon that list.[3] *See, e.g.*, Pls. Br. at 3; Compl. ¶¶ 186, 194

[3] Notably, this scope of requested relief also runs afoul of Article III limits. To the extent Novo asks this Court to set aside the selection of *other* companies' drugs for negotiation, that relief is overbroad and unnecessary to remedy the injuries Novo alleges to suffer. *See, e.g., DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 335 (2006) (explaining the established rule that "a plaintiff must demonstrate standing separately for each form of relief sought" (citation omitted)). The Court is without constitutional or equitable authority to grant such relief. *See generally Hollingsworth v. Perry*, 570 U.S. 693, 708 (2013) ("[I]n the ordinary course, a litigant must assert his or her own legal rights and interests, and cannot rest a claim to relief on the legal rights or interests of third parties" (citation omitted)).

(requested relief for the two statutory claims); *see also id.* at 59 (prayer for relief). Granting this relief would thus undo the very determination that Congress shielded from review under the plain text of the statute.

Trying to evade this explicit bar on judicial review, Novo argues that it is challenging the "number" of drugs that CMS selected for negotiation pursuant to § 1320f-1(a)(1), which it contends is not a determination that Congress expressly shielded from review. Pls. Br. at 30-31. But this attempt to plead around the jurisdictional bar collapses upon examination. As explained in more detail below, *infra* Section II.A, CMS's selection of Novolog derives from CMS's determination that all the selected formulations of Novo's insulin aspart constitute a single "qualifying single source drug" under § 1320f-1(e) because they share the same "active ingredient." Novo's first ultra vires claim asserts that this determination misinterprets how Congress intended the agency to treat products with separate U.S. Food and Drug Administration (FDA) approvals. Pls. Br. at 19-21; *see also* Compl. ¶¶ 189, 191-92. And Novo's second—broader—claim asserts that CMS was without authority to promulgate substantive standards like the "active ingredient" methodology through the Revised Guidance at all. *See* Pls. Br. at 36-37. Thus, both the narrower FDA-approval argument and the broader rulemaking claim don't just target the number of drugs CMS selected—instead, both seek to undo CMS's "qualifying single source drug" determination, albeit in different ways. But CMS's "determination of qualifying single source drugs" under § 1329f-1(e) is itself one of the precursor determinations to CMS's "selection of drugs" that Congress explicitly made unreviewable. 42 U.S.C. § 1320f-7(2). The Court therefore cannot review either of Novo's statutory claims due to the IRA's jurisdictional bar.

Put another way, Novo's statutory challenges do not arise from or contest a legal framework distinct from CMS's "selection of drugs," its "determination of negotiation-eligible drugs," or its "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). Rather, both of Novo's claims seek to reverse those (unreviewable) decisions. Granting even narrow relief only with respect to Novo's drug would disrupt CMS's ongoing negotiations—and make it impossible for the agency to select another drug in time to comply with the established statutory deadlines. *See generally* Revised Guidance at 91-92 (outlining statutory timetable).

Congress was plainly concerned with this type of disruption to the Negotiation Program and attuned to the possibility that manufacturers could undermine the soundness of the program by seeking to undo the selection of their drugs months or even years after the fact. Accordingly, Congress barred such review—both with respect to the ultimate selection of individual drugs, and with respect to the manner in which the agency makes those individual selections. That was a deliberate policy choice by Congress, and it must be given effect.

2. This conclusion is reinforced by a well-settled body of precedent interpreting similar preclusion bars in other parts of the Medicare statute. Such bars are not unusual and—unsurprisingly—plaintiffs have long sought ways to argue around their application. But courts have consistently rejected such efforts.

For example, in *Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012), the D.C. Circuit construed a statute barring review of "the awarding of contracts" to cover challenges to a regulation setting forth eligibility standards for contracts, which it found to be "indispensable to 'the awarding of contracts.'" *Id.* at 409 (citation

omitted). In doing so, the court specifically declined to "distinguish between an upfront attack . . . by suppliers not yet injured by [the rule] and a challenge brought after-the-fact by a frustrated bidder." *Id.* at 410.

Likewise, the D.C. Circuit recently affirmed that a statutory bar against "administrative or judicial review" of "[a]ny estimate of the Secretary for purposes of determining [specified statutory] factors" barred plaintiffs from challenging "'the methodology adopted and employed' by HHS to calculate" one of those factors. *DCH Reg'l Med. Ctr.*, 925 F.3d at 505. As the court explained, a "distinction between methodology and estimates would eviscerate the statutory bar" against review, since "almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.* at 506. Because the "method" used was "inextricably intertwined" with the "estimate," the court concluded that the statute "precludes review of both." *Id.* at 507.

This approach is common. Courts regularly find that preclusion provisions bar decisions that are "'indispensable' or 'integral' to, or 'inextricably intertwined' with, the unreviewable agency action." *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016) (citing *Tex. All. for Home Care Servs.*, 681 F.3d at 409-10); *see also Knapp Med. Ctr.*, 875 F.3d at 1130-31 (applying same standard); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (a statute barring judicial review of "prospective payment rates" covers "adjustments used to calculate th[ose] rate[s]"); *DCH Reg'l Med. Ctr.*, 925 F.3d at 507 (canvassing cases). And this standard applies no less where plaintiffs cast their claims as contesting some procedural irregularity. *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 19, 26 (2d Cir. 2022) (finding that prohibition against "judicial review" of "estimates" precluded a claim that the Secretary "failed to abide by adequate

notice-and-comment rulemaking procedures" before selecting underlying data). As the Second Circuit has explained, where Congress precludes review of a particular determination, courts "may not 'inquire whether' [the determination] . . . was the result of a 'procedurally defective' notice-and-comment rulemaking process any more than we may question actions by the Secretary that were 'arbitrary, capricious,' or otherwise substantively 'defective.'" *Id.* at 26.

These principles are equally applicable here. As explained above, Novo is seeking to set aside CMS's selection of its drug by arguing that the underlying methodology was contrary to the statute and improperly promulgated. But the methodology Novo challenges substantively and procedurally is "'inextricably intertwined' with the" determinations Congress expressly insulated from review. *DCH Reg'l Med. Ctr.*, 925 F.3d at 507 (citation omitted); *see also Yale New Haven Hosp.*, 56 F.4th at 19. Most obviously, the number of drug products that CMS selected is a direct consequence of its determination of what constitutes a "qualifying single source drug." Accordingly, Novo's efforts to read the jurisdictional bar as applying "only to CMS's application of the statutory requirements to the data and information [CMS] is authorized to collect"—a reading which does not track the language of the statute and which Novo does not even attempt to justify based on the plain text—is unavailing. Pls. Br. at 31. CMS's selection of drugs necessarily "subsume[s]" the methods by which CMS selects those drugs. *American Clinical*, 931 F.3d at 1206. Novo thus seeks to "do[] exactly what the plaintiffs in *Florida Health* and *DCH Regional* did: complain[] about the method that was used" to make a determination that Congress exempted from review. *Scranton Quincy Hosp. Co., LLC v. Azar*, 514 F. Supp. 3d 249, 262 (D.D.C. 2021).

3. Novo cannot escape this result by characterizing its two statutory claims as contesting an "ultra vires" construction of the statute. Pls. Br. at 33. Courts have repeatedly explained that such attempts to "[d]esign[] a pleading so that it circumvents a statutory bar to review will not override Congress's decision to deny jurisdiction." *Mercy Hosp.*, 891 F.3d at 1067. And "the repetition of the mantra '*ultra vires*' does not help." *Scranton Quincy Hosp.*, 514 F. Supp. 3d at 264.

As the D.C. Circuit has observed, the precedent on which courts have sometimes relied to entertain ultra vires claims notwithstanding jurisdictional bars stands in tension with recent Supreme Court decisions. *DCH Reg'l Med. Ctr.*, 925 F.3d at 509 (discussing *Board of Governors of the Federal Reserve System v. MCorp Financial, Inc.*, 502 U.S. 32 (1991) and prior cases). Under those recent precedents, "there is not much room to contend that courts may disregard statutory bars on judicial review just because the underlying merits seem obvious." *Id.* "At most," such claims may proceed "only when three requirements are met: '(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l Med. Ctr.*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. Of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009), (cleaned up)); *see also Yale New Haven Hosp.*, 56 F.4th at 26 (same).

Here, of course, the statute *expressly* precludes review of the challenged determination—so the first requirement is lacking. That is sufficient to reject both of Novo's statutory challenges. *Yale New Haven Hosp.*, 56 F.4th at 27 (because the statute "*expressly* precludes review," plaintiffs' "ultra-vires challenge fails"). As noted above, although

Novo, at times, characterizes its first ultra vires claim as challenging CMS's selection of more drug products than what (Novo claims) the statute authorizes, that challenge is merely a dispute with CMS's determination of what products constitute a single "qualifying single source drug," which is itself an unreviewable determination. 42 U.S.C. § 1320f-7(2). The same is true of Novo's second claim that CMS lacked authority to promulgate its approach through guidance. Further, Novo does not come close to meeting the third factor, which "covers only 'extreme' agency error, not merely '[g]arden-variety errors of law or fact.'" *DCH Reg'l Med. Ctr.*, 925 F.3d at 509 (quoting *Griffith v. Fed. Labor Rels. Auth.*, 842 F.2d 487, 493 (1988)). The underlying merits of both claims do not fall in Novo's favor at all, much less "plainly" so. *See infra* Section II. To allow review of those claims would thus disregard Congress's express jurisdictional bar several times over.

In short, this Court lacks subject-matter jurisdiction to consider Novo's statutory claims because the IRA contains a "provision that precludes [such] judicial review." *Yale New Haven Hosp.*, 56 F.4th at 16-17 (quoting *Knapp Med. Ctr.*, 875 F.3d at 1128). Counts III and IV of Novo's complaint must therefore be dismissed.

II. NOVO'S STATUTORY CHALLENGES FAIL ON THE MERITS

Even if the Court had subject-matter jurisdiction to review Novo's statutory claims, those claims would fail on the merits. CMS's selection of Novo's drug is consistent with the plain text and structure of the IRA. And as for process, Congress explicitly authorized CMS to implement the Negotiation Program "by program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c).

A. CMS's Selection of Multiple Forms of the Same Drug Correctly Implements the IRA

CMS's selection of the various forms of Novolog for negotiation flows from the agency's interpretation of what constitutes a "qualifying single source drug" under 42 U.S.C. § 1320f-1(e)(1). As CMS explained in § 30.1 of the Revised Guidance, in identifying whether a biologic like Novolog constitutes "a potential qualifying single source drug," CMS will consider "all dosage forms and strengths of the [] product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclu[ding] products that are marketed pursuant to different BLAs." Revised Guidance at 99. Because the formulations of Novolog satisfied this definition—and met the other statutory criteria—CMS determined that it was one "qualifying single source drug," and thus eligible for negotiation.

Protesting this approach, Novo contends that various contextual clues in the IRA prohibit CMS from selecting more than 10 "different *products*," as that term is understood by FDA in administering the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA). Pls. Br. at 19 (emphasis added). But, as CMS correctly explained in its Revised Guidance, Novo's interpretation is irreconcilable with the IRA's text, structure, and goals.

1. Congress Did Not Adopt a Product-Specific Definition of Drug in the IRA

In establishing threshold criteria for a "qualifying single source drug," Congress specified that it must be a "covered part D drug" that is approved—or a "biological product" that is licensed—by the FDA. 42 U.S.C. § 1320f-1(e)(1) (citing 42 U.S.C. § 1395w-102(e)). Generally speaking, FDA approves drugs and biologics on a product-by-product basis, so a new version of a drug or biologic might receive its own approval

in a separate application or license. *See* Pls. Br. 19; 21 U.S.C. § 355(a) (approval requirement for "new drugs"); 21 C.F.R. § 314.3(b) (defining "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance"). But, as Novo's own submissions indicate, FDA often approves multiple drug products under a single NDA or BLA. *See, e.g.*, Declaration of Karen N. Hauda, ECF 29 at ¶¶ 30, 38 (noting that multiple Novolog products are approved under one BLA and that multiple Fiasp products are approved under a different BLA). And, in establishing what constitutes a "drug," the IRA draws no distinction between those circumstances, nor how many products, applications, or licenses FDA reviewed.

To the contrary, Congress expressly referred to different dosage forms, strengths, and formulations—which in many instances cannot exist except as distinct products, and which might be approved under different applications—as a singular "drug." *See* 42 U.S.C. § 1320f-1(d)(3)(B). For example, Congress provided that, "in determining whether a qualifying single source drug" is "negotiation eligible" under section 1320f-1(d), CMS "shall use data that is aggregated across dosage forms and strengths of *the drug*, including new formulations of *the drug*, such as an extended release formulation." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added); Revised Guidance at 99. Once CMS selects a drug for negotiation, CMS is required to consider all "*applications and approvals* [plural]. . . for the *drug* [singular]" as a relevant factor when devising the government's price offer for that drug. *See* 42 U.S.C. § 1320f-3(e)(1)(D) (emphases added). And, once negotiations are completed and a price is established, CMS is required to "apply the maximum fair price across different strengths and dosage forms of

a selected drug and not based on the specific formulation or package size or package type of such drug." 42 U.S.C. § 1320f-5(a)(2) (emphasis added).

These repeated references to the possibility that a single negotiation-eligible drug would comprise multiple dosage forms, strengths, and formulations—and have multiple FDA approvals—would make no sense if Congress had intended CMS to follow FDA's product-specific approach to drug and biologics applications under the FDCA and PHSA. CMS could not, for example, treat all "new formulation[s]" as part of the same (singular) "drug"—as the IRA requires—if CMS were bound to treat products in separate NDAs or BLAs separately. 42 U.S.C. § 1320f-1(d)(3)(B). Nor, by Novo's logic, could CMS even consider products approved under a *single* NDA or BLA (such as different strengths) to be the same drug, contrary to the IRA's express requirements. *See* Pls. Br. at 24; *see generally Corley v. United States*, 556 U.S. 303, 314 (2009) ("[O]ne of the most basic interpretive canons, [is] that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004))). As CMS correctly observed, the suggestion that "a qualifying single source drug [] refer[s] to a distinct NDA or BLA," much less to distinct products, "is inconsistent with" the data-aggregation requirements in "sections 1192(d)(3)(B) and 1196(a)(2) of the Act." Revised Guidance at 11.

The IRA thus "necessarily establish[es] that the statutory negotiation procedures apply more broadly than to a distinct NDA or BLA"—and certainly more broadly than individual products *within* a single NDA or BLA. *Id.* CMS's approach of looking to whether different drug products or biological products share "active moieties" or

"active ingredients," respectively, properly accounts for the statutory structure. Specifically, looking to whether different products share "active moieties" or "active ingredients" allows CMS to distinguish truly new and innovative therapeutics from merely new versions of existing treatments. Doing so is "consistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act, [and] gives effect to the statutory policy that a drug that may be selected for negotiation includes multiple dosage forms and strengths and formulations of that drug." Revised Guidance at 11-12.

Novo protests that Congress did not "mention active moieties or active ingredients" in the IRA. Pls. Br. at 26. But the IRA does not directly define the term "drug" either, much less mandate that CMS follow the FDA's approach in implementing a different statute that Congress drafted differently. *See* 42 U.S.C. § 1320f(a)-(c). Even so, CMS did not pluck the terms "active moiety" and "active ingredient" from thin air. The terms have a long history and prominent role in FDA's practice, where among other things, the term "active moiety" is used as a proxy for innovation in drug development. *See, e.g.*, 21 C.F.R. § 314.3 (defining both terms); Pub. L. No. 117-9, 135 Stat. 256 (2021) (codifying FDA's definition); *see also, e.g.*, *Defining Active Ingredient,* https://crsreports.congress.gov/product/pdf/R/R46110. Contrary to Novo's assumption, Congress did not need to explicitly specify the terms "active moiety" or "active ingredient" for CMS to rely upon them. Pls. Br. at 29 (citing provisions of the FDCA). The statutory requirement of aggregation suggests that Congress intended CMS to adopt something like the "active ingredient" or "active moiety" standard.[4]

[4] Notably, the Congressional Budget Office appeared to understand that CMS would use an active-ingredient standard. *See* Letter from Phillip L. Swagel, Cong.

Novo also makes the passing (and somewhat cryptic) suggestion that CMS's use of these terms improperly "merge[s]" two distinct regulatory concepts because "drug products may share an active moiety but" have different "active ingredients." Pls. Br. at 25. But CMS has clearly specified when it will consider "active moiety" (drug products) and when it will look to "active ingredient" (biologics). *See* Revised Guidance at 99. Novo provides no basis to believe that this differentiation creates any type of "conflict[]" with FDA's regulatory approach—much less a conflict that would be sufficient to override the text and structure of the IRA. Pls. Br. at 25.

2. CMS's Approach is Consistent with the IRA's Other Provisions

Trying a different tack, Novo alleges that treating multiple products as a single "qualifying single source drug" is inconsistent with (1) the IRA's provisions defining how long a drug must be on a market before it can be selected; (2) the distinction the IRA draws between Part B and Part D drugs; and (3) broader policy objectives. Pls. Br. at 21-23. But Novo is mistaken on all counts.

First, the fact that the IRA defines a qualifying single source drug as one approved by the FDA and for which "at least 7 years will have elapsed since the date of such [NDA] approval" (or 11 years for BLA licensure), does not mean that the IRA necessarily contemplates only a singular "approval" for each drug. A qualifying single source drug may have several different NDAs or BLAs yet still have a single *relevant* approval or licensure date. As CMS explained, it "will use the earliest date of approval

Budget Off. (Dec. 21, 2023), https://www.cbo.gov/system/files/2023-12/59792-Letter.pdf. While certainly not dispositive of Congress's intent, this understanding demonstrates that the concepts were familiar and CMS's use of them not unexpected.

or licensure of the initial FDA application number assigned to the NDA / BLA holder." Revised Guidance at 101. This explanation once again properly accounts for the inter-play between the definition of "qualifying single source drug" in 1320f-1(e)(1) and the data-aggregation provisions in sections 1320f-1(d)(3)(B) and 1320f-5(a)(2). Indeed, in directing CMS to aggregate different "dosage forms and strengths of *the drug*, including new formulations of *the drug*," Congress pointedly did *not* specify a minimum length of time that each particular dosage form, strength, or formulation had to be approved or licensed. 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). To the contrary, the statutory text explicitly requires the agency to include "new formulations" in its calculations. *Id.* The plain import of these provisions is that CMS should *not* exclude new formulations of a drug or biologic from the "qualifying source drug" definition even if those later versions have not been approved or licensed for as long as the original formulation of the drug.

This understanding also defeats Novo's related claim that CMS's approach of treating multiple products with the same active ingredient or active moiety as the same drug renders the statutory data-aggregation provisions "nonsensical." Pls. Br. at 28. Contrary to Novo's suggestion, the statutory aggregation provision has real meaning under CMS's interpretation: among other things, it clarifies that products like Novolog may not be excluded from the Negotiation Program merely because an application holder reformulates the same active ingredient into a new product.[5] Were it otherwise,

[5] In any event, even if CMS's approach were to lead to some redundancy that would be "no cause for alarm." *Mercy Hosp.*, 891 F.3d at 1068. "A little overlap, either by accident or design, is to be expected in any complex statutory scheme with

a manufacturer of a selected drug could attempt to circumvent the Negotiation Program by shifting production over to a product with the same active moiety or active ingredient but, for example, a different dosage form. Doctors would thus continue to prescribe what is essentially the same drug and Medicare would continue to provide reimbursement at current prices, solely because a manufacturer offered a new form of the same treatment.

CMS properly recognized that nothing in the statutory text allows (let alone requires) the goals of the IRA to be so easily undermined. As CMS detailed in the Revised Guidance, aggregating across different dosage forms and strengths for the same drug, including new versions of that same drug from the same manufacturer, "will decrease incentives for pharmaceutical manufacturers to engage in 'product hopping,'" Revised Guidance at 12—*i.e.*, the practice of seeking to maintain market exclusivity and high prices by switching patients from an old version of a drug product "to a new version, which may not offer any improvements in effectiveness or safety." *See* H.R. Rep. No. 116-695, at 3 (2020). Given that lowering the costs of Medicare drugs was the primary goal of the IRA, it is implausible that Congress intended to incentivize manufacturers to continue engaging in such practices.

Second, Novo's claim that the selection of its insulin products for the first round of negotiations erases the IRA's distinction between Part B and Part D drugs is similarly unavailing. Pls. Br. at 23. The IRA simply directs CMS to select drugs based on relative

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interdependent provisions." *Id.* (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 699 (D.C. Cir. 2014)). Novo cannot undo an otherwise reasonable interpretation on so thin a reed.

spending—and makes only Medicare Part D spending a relevant ranking criterion for price applicability years 2026 and 2027. 42 U.S.C. § 1320f-1(a)(1) (directing CMS to select 10 drugs under § 1320f-1(d)(1)(A)); *id.* § 1320f-1(d)(1)(A) (directing CMS to rank drugs based on "total expenditures under part D of" the SSA). Contrary to Novo's suggestion, for purposes of this calculation, it is immaterial in the first two years of the program whether a particular drug might also be reimbursed under Part B. Rather, the practical effect of the IRA's provisions is that a drug with Part B expenditures would not be selected *unless* it ranks among the highest Part D expenditures. Novolog happened to fit this criterion. But Novo can point to no statutory language that would *exempt* the drug merely because it might *also* receive some Part B reimbursement.

Novo also asserts, in conclusory terms, that CMS's selection of Novolog "violates the IRA's high-spending requirements." Pls. Br. at 23. Tellingly, however, Novo does not articulate an independent statutory provision that CMS has violated. Rather, Novo's this argument is entirely derivative of Novo's claim that CMS was required to treat each formulation of Novolog as a separate "drug" for purposes of the Negotiation Program. But, as explained above, Congress adopted a different approach.

Third, and finally, Novo protests that CMS's approach "incentivizes manufacturers not to innovate." Pls. Br. at 18. This argument, however, fails to establish that CMS has contravened the statute: the same could be said of any regulatory or statutory change that places *any* downward pressure on future pharmaceutical profits. Further, as courts have recognized, adopting an approach that allows manufacturers to product hop "may *deter* significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the

research and development necessary to develop riskier, but medically significant innovations." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015) (emphasis added).

Ultimately, Novo's objections on these grounds are nothing more than a policy disagreement with the IRA generally. But Novo cannot premise a statutory challenge on mere disagreement with how Congress weighed competing policy concerns. The only appropriate forum for that argument is Congress.

B. Congress Expressly Authorized CMS to Implement the IRA Through Guidance for the First Three Cycles

Having failed to establish an actual conflict between CMS's approach and the IRA, Novo tries for a broader argument. In Novo's view, *all* of the interpretations and methodologies CMS articulated in the Revised Guidance should be set aside because they are substantive standards—and, Novo contends, Congress stripped CMS of the authority to promulgate substantive rules when it directed the agency to implement the Negotiation Program through "guidance" for the first three negotiation cycles. Pls. Br. at 34; *see* § 11001(c), 136 Stat. at 1854. But here again Novo misreads the statute.

Congress enacted the IRA against the background of the Medicare Act, which generally grants the Secretary authority to "prescribe such regulations as may be necessary to carry out the administration of" Medicare programs. 42 U.S.C. § 1395hh(a)(1). When such regulations would "establish[] or change[] a substantive legal standard," the Secretary is generally required to proceed through notice-and-comment rulemaking. *Id.* § 1395hh(a)(2). That provision supplements the APA's requirement for agencies to engage in notice-and-comment rulemaking when issuing legislative rules. *See* 5 U.S.C.

§ 553(b); *see generally Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019). But both the Medicare Act and the APA explicitly contemplate situations in which Congress "expressly" authorizes agencies to conduct rulemaking without following those procedures. 5 U.S.C. § 559; *see also* 42 U.S.C. § 1395hh(b)(2)(A) (similar). The Supreme Court has emphasized that "the word 'expressly' does not require Congress to use any 'magical passwords' to exempt a later statute from the provision." *Dorsey v. United States*, 567 U.S. 260, 274 (2012) (quoting *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)). Rather, "the Court has described the necessary indicia of congressional intent by the terms 'necessary implication,' 'clear implication,' and 'fair implication.'" *Id.* (citing *Great Northern R. Co. v. United States*, 208 U.S. 452, 465, 466 (2012); *Hertz v. Woodman,* 218 U.S. 205, 218 (1910); *Warden v. Marrero,* 417 U.S. 653, 660 n.10 (1974)). The requisite intent can be found when, for example, Congress "specifie[s] procedures . . . that cannot be reconciled with the notice and comment requirements of" the APA or the Medicare Act. *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998).

That is what Congress did in the IRA. By directing CMS to "implement the [Negotiation Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance," § 11001(c), 136 Stat. at 1854, Congress "specifie[d] procedures which differ from those of the APA" and the Medicare Act. *Asiana Airlines*, 134 F.3d at 398; *see also Transpacific Steel LLC v. United States*, 4 F.4th 1306, 1321 (Fed. Cir. 2021) (noting that "implement" means "[t]o provide a definite plan or procedure to ensure the fulfillment of"). Rather than requiring CMS to proceed through notice and comment, Congress authorized CMS to promulgate substantive standards *without* observing those procedures. *Id.* There was good reason to do so. The IRA was enacted on

August 16, 2022, yet directed CMS to publish the list of selected drugs for price applicability year 2026 by September 1, 2023, *see* 42 U.S.C. §§ 1320f(b)(3), (d)(1), and to enter into the first agreements with participating manufacturers of selected drugs by October 1, 2023, *see id.* §§ 1320f(a)(2), (d)(4). To achieve those deadlines, CMS is required to make numerous determinations—and Congress recognized that spelling out the methodological details for those determinations through full notice-and-comment rulemaking might prove impossible within the tight statutory timeframes. Congress therefore expressly authorized CMS to forgo those procedures in the Negotiation Program's early years. *Cf. Allina*, 139 S. Ct. at 1816 (recognizing Congressional authority to alter notice-and-comment requirements for rulemaking under the Medicare Act). [6]

Novo's reading, by contrast, would turn Congress's evident intent on its head. Rather than granting a dispensation from notice-and-comment requirements in light of the expedited schedule of the first several negotiation cycles, Novo claims that Congress intended to *preclude* the agency from engaging in *any* kind of rulemaking at all. Pls. Br. at 34-35. Of course, the plain text of the IRA contains no express revocation of the longstanding rulemaking authority Congress granted to the agency in 42 U.S.C.

[6] Despite this dispensation, CMS still voluntarily solicited and considered extensive comments on various aspects of the Guidance as a way of ensuring that it would not overlook important considerations. The Initial Guidance stated that "CMS is voluntarily soliciting comments" on all relevant sections, including on "the "[t]erms and conditions contained in the manufacturer agreement." Initial Guidance at 5; *see also* Revised Guidance at 30. And CMS exhaustively responded to these comments and made changes in response to input. *See* Revised Guidance at 8–91; *see, e.g.*, *id.* at 31, 120 (revising policy regarding providing points of contact); *id.* at 33, 120–21 (revising policy to clarify voluntary termination procedures); *id.* at 125 (adding new section on opportunity for corrective action); *id.* at 128 (clarifying compliance and monitoring requirements); *id.* at 129 (clarifying termination requirements).

§ 1395hh(a)(1). *See* IRA 11001(c), 136 Stat. at 1854. So Novo seeks to infer such a revocation from the fact that Congress did not mention notice-and-comment rulemaking at all—and instead stated that the agency shall "implement" the program through "instruction" or "guidance" for the first three negotiation cycles. *Id.* Novo's argument thus comes down to an assertion that Congress revoked CMS's longstanding Medicare rulemaking authority *sub silentio*. But, as the Supreme Court has made clear, there is a "'stron[g] presum[ption]' that repeals by implication are 'disfavored' and that 'Congress will specifically address' preexisting law when it wishes to suspend its normal operations in a later statute." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (quoting *United States v. Fausto,* 484 U.S. 439, 452, 453 (1988)). And here, Congress's silence about CMS's general rulemaking power falls far short of establishing a "clear and manifest" intent to repeal CMS's existing authority. *Id.* (citation omitted).

Further, Novo's interpretation would lead to such absurd results that it should be rejected. *See Douglass v. Convergent Outsourcing*, 765 F.3d 299, 302 (3d Cir. 2014) ("[W]e are obligated to 'construe statutes sensibly and avoid constructions which yield absurd or unjust results.'" (quoting *United States v. Fontaine,* 697 F.3d 221, 227 (3d Cir. 2012)); *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575, 102 S. Ct. 3245, 3252, 73 L. Ed. 2d 973 (1982) ("[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available."). As the very cases Novo cites confirm, rulemaking is a well-established feature of federal programs. *See, e.g.*, *Kisor v. Wilkie*, 139 S. Ct. 2400, 2410-11 (2019) (providing examples of areas where agencies regulate). No matter how precise or detailed a

statutory regime, neither Congress nor agencies can anticipate all of the difficulties and nuances that may arise during its implementation. *Id.*

The IRA is no exception. Indeed, in charging the Secretary with the responsibility to implement the Negotiation Program, Congress repeatedly instructed the Secretary to exercise his judgment in making various determinations without specifying the precise methodology. *See*, 42 U.S.C. § 1320f-2(a)(5) (requiring manufacturers that enter into negotiation agreements to "comply with requirements determined by the Secretary to be necessary for purposes of administering the program"); *see also, e.g., id.* §§ 1320f-1(b) (negotiation-eligible drugs to be ranked by total expenditures "as determined by the Secretary"); 1320f-1(c) (Secretary to determine when standard for generic competition is met for a selected drug); 1320f-2(a) (participating manufacturer to submit "information that the Secretary requires to carry out" the negotiation process). Novo itself contends that such methodologies can amount to substantive standards. It is "implausible that Congress meant" the Secretary to establish such standards yet simultaneously precluded him from doing so by silently *rescinding* CMS's preexisting rulemaking authority. *King v. Burwell*, 576 U.S. 473, 494 (2015).

Tellingly, Novo cites no precedent interpreting an *authorization* for an agency to implement a program through guidance as also *repealing* an agency's preexisting authority to engage in rulemaking. *See* Pls. Br. at 34-36. Nor, for that matter, does Novo articulate any "good reason" why it would make sense for Congress to outright *preclude* CMS from engaging in rulemaking for the first three negotiation cycles. *Id.* at 37. If, as Novo posits, Congress did not want to waive the typical notice-and-comment requirements and additionally wanted to constrain CMS's rulemaking discretion, there

were much more straightforward ways to do that. Most obviously, Congress could have explicitly rescinded CMS's general Medicare rulemaking authority for purposes of implementing the IRA; alternatively, it could have expressly set forth the categories on which CMS could and could not engage in rulemaking. Congress did none of those things. Instead, it broadly directed CMS to "implement" the program through expedited procedures in the early years. CMS's Revised Guidance does just that.[7]

* * *

Novo's statutory challenges to CMS's implementation of the IRA fail to overcome the jurisdictional bar Congress established in § 1320f-7 and, in any event, fail on the merits. Those challenges should be dismissed.

III. NOVO'S FIFTH AMENDMENT CLAIM FAILS ON THE MERITS BECAUSE THE NEGOTIATION PROGRAM IS VOLUNTARY

Novo's Fifth Amendment challenge follows a familiar playbook. Hospitals, nursing homes, and other providers have, for decades, raised similar arguments against other limits on Medicare reimbursements—and courts have, for decades, rejected such claims. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) ("All court decisions of which we are aware that have considered [Fifth Amendment] challenges by physicians to Medicare price regulations have rejected them in the recognition that

[7] Notably, Novo's contrary position is of recent vintage. As noted above, CMS voluntarily solicited comments on its implementation of the Negotiation Program. In its comment, Novo asserted that CMS *did* have the authority to engage in notice-and-comment rulemaking, and encouraged the agency to undertake that effort. *See* Letter from Jennifer Duck, VP, Public Affairs, Novo Nordisk, to Meena Seshamani, Deputy Admin'r, CMS, at 6-7 (Apr. 14, 2023), available at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation (click link titled "Public Comments: Medicare Drug Price Negotiation Program Initial Guidance").

participation in Medicare is voluntary." (collecting cases)); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (same). The "law established" in those cases "is clear:" because "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," "the consequences of that participation cannot be considered a constitutional violation." *Chamber*, 2023 WL 6378423, at *11 (citations omitted). And this principle, as the *Chamber* court correctly held, applies equally to the Negotiation Program. *Id.*

Contrary to Novo's contentions, neither the IRA nor any other part of Medicare "legally compel[s]" manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries. *Id.* "[P]harmaceutical manufacturers who do not wish to participate in the [Negotiation] Program have the ability . . . to opt out" in several different ways. *Id.* Like other Medicare reimbursement limits, the Negotiation Program reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant—and raises no Fifth Amendment concerns.

A. The Negotiation Program Does Not Compel Participation

The Due Process Clause of the Fifth Amendment protects against improper deprivations of "property." U.S. Const. amend. V. But it is well established that a "property owner must be *legally compelled* to engage in price-regulated activity for [those] regulations to" impugn a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see, e.g., Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944) (rent controls do not constitute prohibited taking because statute did not require landlords to offer their apartments for rent). When an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and

thus there can be no" deprivation of property. *Garelick*, 987 F.2d at 916 (citing cases); *Franklin Mem'l Hosp.*, 575 F.3d at 129 ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). And that is the case with limits on Medicare spending, like the kind Congress sought to achieve with the Negotiation Program. *See Chamber*, 2023 WL 6378423, at *11.

As courts have repeatedly explained, "participation in Medicare is voluntary." *Garelick*, 987 F.2d at 917; *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869-70 (6th Cir. 1986) (same); *see also Baker Cnty.*, 763 F.3d at 1279-80 (surveying cases); *see generally Chamber*, 2023 WL 6378423, at *11 (discussing this precedent). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statutory provision *requires* entities to participate in Medicare or to sell their property. *Garelick*, 987 F.2d at 916. So, whether confronting regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: entities are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government will reimburse. *Baptist Hosp.*, 802 F.2d at 869-70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cnty.*, 763 F.3d at 1279-80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129-30; *Garelick*, 987 F.2d at

916-19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the Fifth Amendment."). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869-70. There is no legal compulsion to participate.

The Negotiation Program is no different. *See Chamber*, 2023 WL 6378423, at *11. The IRA regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that elect not to participate in Medicare and Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax consequences are only applicable if the manufacturer continues to participate in Medicare and Medicaid). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid programs. *See Chamber*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33-34, 120-21, 129-31. Alternatively, a manufacturer can divest its interest in the selected drug to a separate entity—or otherwise stop selling it to Medicare beneficiaries, permanently or temporarily, which would expose it to no penalty or tax under the IRA. *Id.* at 131-32.

Thus, contrary to Novo's claims, manufacturers "are not legally compelled to participate in the Program" or forced to make sales they don't want to make. *Chamber*, 2023 WL 6378423, at *11. Unlike laws requiring utilities to serve the public, the IRA does not "compel[] [manufacturers] to employ their property to provide [drugs] to" Medicare beneficiaries—at any price. *Garelick*, 987 F.2d at 916. Rather, a manufacturer of a selected drug is *only* required to provide "access" to negotiated prices if it *chooses* to participate in Medicare and make its drugs available for Medicare coverage. As courts have explained in rejecting Fifth Amendment challenges to other Medicare conditions, "[i]f any provider fears that its participation [in the program] will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70. That choice is the manufacturer's to make.

B. Manufacturers Have Adequate Opportunity to Withdraw from the Program

Attempting to evade this well-settled precedent, Novo asserts that the IRA makes it impossible for manufacturers to withdraw from the Negotiation Program without incurring a sizeable tax or a penalty. Pls. Br. at 56-57. This argument rings hollow. Novo has not indicated that it wishes to withdraw from the Negotiation Program or from Medicare and Medicaid, so its complaints about the process for withdrawal are purely academic. *See* Pls. Br. at 56-57. But regardless, these arguments fail because Novo misunderstands the IRA's terms.

Section 11003 of the IRA provides that manufacturers will incur no tax if they cease participating in Medicare and Medicaid prior to the statutory deadline to enter into an agreement to negotiate—or, if they have initially agreed to negotiate (as

manufacturers of all selected drugs now have), prior to the statutory deadline to enter into a final pricing agreement with CMS. *See* 26 U.S.C. § 5000D(b)(1)-(2) (defining periods when tax would take effect); *id.* § 5000D(c)(1)(A)(i)-(ii) (providing that the excise tax will be suspended "beginning on the first date on which" "none of the drugs of the manufacturer" are covered by Medicare).[8] The Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS in 30 days for "good cause." *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on these provisions, CMS's Revised Guidance explains that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days. Revised Guidance at 130. As a result, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33-34.

That timeline provides manufacturers flexibility to "opt out" of the Negotiation Program. *Chamber*, 2023 WL 6378423, at *11. Manufacturers of the first 10 selected drugs had 34 days to decide whether they wanted to negotiate with CMS before any tax liability (for selling the drug to Medicare without signing an agreement to negotiate)

[8] Section 5000D(c) also conditions suspension of the tax on a manufacturer giving notice of termination of its drug rebate agreement under Medicaid. 26 U.S.C. § 5000D(c)(2).

could be triggered. *See* 42 U.S.C. § 1320f(d)(1) (requiring first list of drugs for negotiation to be published by September 1, 2023);[9] 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent manufacturer signing agreement to negotiate). Novo, along with the manufacturers of all the other selected drugs, signed agreements to negotiate. *See Manufacturer Agreements* at 1. Manufacturers will know how those negotiations are going far in advance of August 2, 2024, when they could first be exposed to tax liability if they have not signed a final price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if a manufacturer signs a final price agreement before the statutory deadline, there are still *at least 17 months* before January 1, 2026, when any negotiated prices would first take effect—and any civil penalty (but no tax) could even possibly be triggered. 42 U.S.C. § 1320f-6(a) (providing for civil monetary penalties for failing to honor agreement). During this period, the manufacturer can (with 30 days' notice) withdraw from Medicare and Medicaid or can divest its interest in the selected drug. Revised Guidance at 129-32. In this way, a "manufacturer that has entered into an Agreement [] retain[s] the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability." *Id.* at 34.

Novo fails to grapple with these various options. Instead, Novo merely makes passing claims that CMS's use of its own "good cause" authority to provide for the 30-day withdrawal option is inconsistent with the statutory language. Pls. Br. at 57. But Novo itself argues that the absence of an adequate opportunity to withdraw from the Negotiation Program would be unconstitutional—so it can hardly claim that CMS lacks "good cause" to facilitate manufacturers' withdrawal. *See, e.g.*, *United States ex rel.*

[9] In fact, the list was published early, on August 29, 2023.

Polansky v. Exec. Health Res., Inc., 143 S. Ct. 1720, 1730 n.2 (2023) ("good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason"); *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i) (providing for "good cause" termination). That may explain why Novo has not actually challenged CMS's interpretation, which operates to the manufacturers' benefit, and which Novo would therefore lack standing to contest.

Further, even putting aside CMS's Revised Guidance, Novo overlooks the 28-month period between a manufacturer's drug being selected for negotiation and the January 2026 effective date for any negotiated prices. Even by Novo's logic, this delay gives a manufacturer ample time to provide notice of its termination of the relevant Medicare agreements (something it could do even while otherwise engaged in negotiations) and have that termination take effect. *See* Pls. Br. at 56 (claiming that notice must be given "11 to 23 months" in advance); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (providing that a "manufacturer may terminate an agreement under this section for any reason" and that "if the termination occurs before January 30 of a plan year" it shall become effective "as of the day after the end of the plan year").

In short, Novo is wrong to claim that withdrawal from the Negotiation Program is legally impossible or that Congress did not give manufacturers a genuine choice about whether to sell their drugs at negotiated prices. Pls. Br. at 56. The choice "to opt out" of the Negotiation Program is real. *Chamber*, 2023 WL 6378423, at *11.

C. The Negotiation Program Does Not "Coerce" Manufacturers

Unable to show that any manufacturer is *legally* compelled to participate in the Negotiation Program, Novo tries a workaround. Noting that business realities make it difficult to forgo federal Medicare and Medicaid funds, Novo suggests that the Negotiation Program is not voluntary in a looser, more practical sense, and amounts to "severe economic coercion." Pls. Br. at 55-56, 59-60. This argument fares no better.

1. Courts have held that economic or other practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis, including in the Medicare context. *Garelick*, 987 F.2d at 917; *see also St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). So the amount of Novo's sales to Medicare is completely irrelevant to the voluntariness analysis. *Contra* Pls. Br. at 59 (claiming that withdrawing from Medicare and Medicaid would be "economic suicide"). As the court correctly recognized in *Chamber*, this precedent makes clear that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Chamber*, 2023 WL 6378423, at *11 (discussing cases); *see also Baker Cnty.*, 763 F.3d at 1280.

Notably, Novo fails to identify *a single* case agreeing with the premise that Medicare and Medicaid are "coercive" merely because they are lucrative. Pls. Br. at 55-57.

For good reason. Congress enacted Medicare, and imposed conditions on participation, pursuant to its Spending Clause powers. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (internal quotes and citation omitted). A party cannot be coerced by such an offer because there is no "right (or requirement)" to conduct business with the government in the first instance. *Chamber*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd. Of Ill.*, 616 F.2d 341, 342 (7th Cir. 1980); *see also Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (government has authority to "determine those with whom it will deal"); *J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). Just as defense contractors that derive a substantial portion of their revenues from the Department of Defense are free to refuse contracts they find unprofitable, so too drug manufacturers can walk away from the Negotiation Program—even if doing so comes at a cost.

This fact distinguishes Medicare from *regulatory* cases like the ones Novo cites in its brief and on which it builds its coercion theory. Pls. Br. at 55-56; *see, e.g.*, *Horne*, 576 U.S. at 366; *Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937); *Union Pacific R.R. Co. v. Public Service Comm'n of Mo.*, 248 U.S. 67 (1918). Plaintiffs in each of those cases were subject

to regulatory regimes they could not readily exit—and had to comply with the government's conditions if they wished to sell their products to *anyone*. *See, e.g.*, *Horne*, 576 U.S. at 365-66 (raisin growers could not avoid government property demand if they wished to continue selling raisins); *Thompson*, 92 F.2d at 480 (statute fixed the quota of cotton production); *Union Pacific*, 248 U.S. at 67 (plaintiff was subject to statutory prohibitions against issue of a bond unless the prohibition was waived by a state commission). By contrast, the IRA does not prevent manufacturers who are unwilling to participate in the Negotiation Program from selling their drugs to anyone but the government—and those manufacturers would then not need to comply with any of the Negotiation Program's requirements. *See Chamber*, 2023 WL 6378423, at *11. That makes the Program voluntary, and valid.

2. Trying a different tack, Novo seeks to analogize the Negotiation Program to the Medicaid expansion in the Affordable Care Act, which the Supreme Court found to be impermissibly "coercive" in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). Pls Br. at 59-60. But this line of argument reflects a basic misunderstanding of *NFIB*, on several levels.

First, the *NFIB* "coercion" framework addresses—and is derived exclusively from cases analyzing—how *federalism* principles inform what conditions Congress may attach to money it grants *to States*. *See NFIB*, 567 U.S. at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). As the lead opinion in *NFIB* emphasizes, those principles protect "the status of the States as independent sovereigns in our federal system." *Id.* at 577. These federalism-based principles are inapposite in evaluating whether Congress has overstepped its enumerated powers in dealing with private

corporations like Novo. *See, e.g.*, *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, . . . not a federal agency's ability to regulate [private] facilities' use of federal funding"), *cert. denied*, 143 S. Ct. 294 (2022); *see also Northport Health Servs. of Ark., LLC v. HHS*, 438 F. Supp. 3d 956, 970–71 (W.D. Ark. 2020) ("No part of the Court's decision in *NFIB* touched on the government's power to place conditions on private entities.").

Second, inquiring whether Congress has improperly used federal spending to regulate—which is what the *NFIB* "coercion" inquiry analyzes—does not make sense when, rather than using grant conditions to "encourag[e]" States to modify their benefit programs to satisfy federal criteria, Congress has merely set terms for how the federal government will pay for goods in the market. 567 U.S. at 580-81 (quoting *New York v. United States*, 505 U.S. 144, 175 (1992)). Such terms do not seek to end-run limits on Congress's regulatory powers—and any "pressure" Congress may exert through such terms is no different than the leverage of any well-funded market participant, which is of no constitutional import. *Id.* (discussing "coercion" as a limit on Congress's ability to achieve through spending what it cannot achieve directly through regulation). Indeed, the Supreme Court has "long held the view that there is a crucial difference, with respect to constitutional analysis, between the government exercising 'the power to regulate or license, as lawmaker,' and the government acting 'as proprietor.'" *Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (quoting *Cafeteria & Restaurant Workers v. McElroy,* 367 U.S. 886, 896 (1961)). "Where the government is acting as a proprietor,

managing its internal operations, rather than acting as lawmaker with the power to regulate or license, its action will *not* be subjected to the heightened review to which its actions as a lawmaker may be subject." *Int'l Soc. for Krishna Consciousness, Inc. v. Lee*, 505 U.S. 672, 678 (1992) (emphasis added); *Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 79 (1st Cir. 2004) ("[A] lower level of scrutiny usually applies when the government acts as proprietor."). And because "the Government unquestionably is the proprietor of its own funds, when it acts to ensure the most effective use of those funds," such as by setting conditions on their disbursement, "it is acting in a proprietary capacity." *Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002).[10]

Economical and equitable procurement in the market is exactly what Congress sought with the Negotiation Program. Recognizing that American taxpayers spend far too much on high-cost prescription drugs—more than people in any comparable country, for the same drugs—Congress has taken steps to limit how much the government will pay for selected drugs going forward. These steps to limit government spending on selected drugs reflect a valid exercise of Congress's power to "control" federal "spen[ding] according to its view [that] the 'general Welfare'" is best served by reducing taxpayer expenditures on high-cost pharmaceuticals. *NFIB*, 567 U.S. at 579-80; *cf. Sabri*, 541 U.S. at 608 ("The power to keep a watchful eye on expenditures . . . is bound up

[10] Incidentally, these precedents also defeat Novo's efforts to conflate regulatory and proprietary powers. Pls. Br. at 55 (claiming that the "government's power to set prices when it is procuring products for itself . . . does not apply when the government is exercising regulatory powers in a market that it 'dominates'"). Novo cites no case for the proposition that the government's proprietary powers become regulatory merely because the government accounts for a significant portion of a market. Were it otherwise, defense contracting would be subject to entirely different forms of constitutional review.

with congressional authority to spend in the first place."). Such spending conditions are "justified on that basis"—and give rise to no *NFIB*-style "coercion" concerns. *NFIB*, 567 U.S. at 579-80.

Third, the Negotiation Program would not be "coercive" under *NFIB*'s test even if that test were applicable. As the lead opinion in *NFIB* explained, the Spending Clause permits Congress to place "restrictions on the use of [] funds, because that is the means by which Congress ensures that the funds are spent according to its view of the 'general Welfare.'" *Id.* at 580. Such direct restrictions are not subject to the coercion inquiry. *Id.* at 580-81, 584; *see also Miss. Comm'n on Env't Quality v. EPA*, 790 F.3d 138, 179 (D.C. Cir. 2015) (discussing this framework). And here, the Negotiation Program directly "govern[s] the use of" Medicare funds for the selected drugs. As noted above, the conditions Congress established in the Negotiation Program merely constitute limits on how much the government will spend for the drugs CMS selects for negotiation. If a manufacturer does not wish to comply with those limits, it can avoid them by, for example, divesting its interest in the drug. *See* Revised Guidance at 131-32.

Notably, manufacturers *also* have the option of leaving Medicare and Medicaid entirely. For some manufacturers—particularly those that sell only one drug—that may be a more straightforward option. But contrary to Novo's suggestion, the availability of this second choice does not mean that Congress has offered manufacturers anything improper. Pls. Br. at 59-60. Congress routinely conditions Medicare and Medicaid funding on parties observing terms that reach beyond the specific products or services that Medicare reimburses. *See, e.g.*, *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113-16 (2011) (describing the 340B program under 42 U.S.C. §§ 1396r-8(a)(1), which

requires participating drug manufacturers to give steep discounts to various categories of private purchasers); *see also Baker Cty.*, 763 F.3d at 1277-78 (noting that, "[a]s a condition of participating in and receiving payments from Medicare, a hospital must also opt into EMTALA," which generally "requires participating hospitals to provide care to anyone who visits an emergency room"). Similarly, Congress has long required drug manufacturers wishing to participate in Medicaid to enter into agreements with the VA Secretary, which make those manufacturers' covered drugs available for procurement by the VA and other agencies at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). These arrangements have never been found to trigger coercion concerns, and rightly so: suggesting that Medicaid and Medicare conditions unconstitutionally coerce private parties would be contrary to decades of precedent holding that acceptance of such conditions is fully voluntary. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1278-79. Novo provides no basis to believe that *NFIB* upset that settled law.

Indeed, both before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties to accept any conditions. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1280 ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, 'economic hardship is not equivalent to legal compulsion . . . .'" (quoting *Garelick*, 987 F.2d at 917)); *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 209–10 (D.N.J. 2021), *rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023); *see also Minn. Ass'n*, 742 F.2d at 446 (holding that a "strong financial inducement to participate" in a regulated program does not render such participation involuntary); *St. Francis Hosp.*, 714 F.2d at 875. Notably, the Supreme Court recently rejected such an argument when it upheld a COVID-19

vaccination requirement for workers in facilities funded by Medicare or Medicaid, emphasizing that "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions"—despite the challengers arguing that those conditions were coercive under *NFIB*. *Biden v. Missouri*, 142 S. Ct. 647, 652 (2022); *see Biden v. Missouri*, Nos. 21A240, 21A241, Resp. to Stay App. at 27-28 (Dec. 30, 2021) (arguing that the vaccination "condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds" (emphasis in original)).

* * *

By telling manufacturers that Medicare might not continue paying them at current levels for their products, Congress has left them free to choose whether they wish to continue selling the drug to Medicare on new terms. That is not coercion: it is simply an offer made by a buyer to a seller who can then either agree or forgo the sale.

D. The Negotiation Program Is a Proper Condition on Medicare and Medicaid Participation

In a final attempt to avoid the conclusion that the Negotiation Program is "completely voluntary" and thus raises no Fifth Amendment concerns, *Chamber*, 2023 WL 6378423, at *11, Novo asserts that making the program a condition of Medicare and Medicaid participation violates the "unconstitutional conditions doctrine." Pls. Br. at 57-59. According to Novo, Congress has improperly required Novo to surrender due process protections to receive a government benefit. *Id.* But, like Novo's other claims, this one collapses upon examination.

1. The unconstitutional-conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). At a minimum, then, the "predicate for any unconstitutional conditions claim" is the existence of a protected constitutional right that the government's offer would infringe. *Id.* at 612; *see also Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.* (*FAIR*), 547 U.S. 47, 59-60 (2006) ("It is clear that a funding condition cannot be unconstitutional if it could be constitutionally imposed directly."); *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (explaining that while the unconstitutional conditions "doctrine should equally apply to prohibit the government from conditioning benefits on a citizen's agreement to surrender due process rights," the plaintiff must first establish the existence of such a right). And when it comes to an assertion that the government has improperly conditioned a benefit on an entity's surrender of its due process rights, plaintiffs must first establish the existence of a liberty or property interest that the Due Process Clause would protect. *See, e.g.*, *Keego Harbor*, 397 F.3d at 434; *see also Vance v. Barrett*, 345 F.3d 1083, 1090 (9th Cir. 2003) (same). That is, a plaintiff must demonstrate that the government is seeking to leverage a discretionary benefit against a *separate* vested property interest. *Keego Harbor*, 397 F.3d at 434.

Here, however, Novo can identify no distinction between the benefit and the right that is supposedly being leveraged. As Novo itself explains, the valuable "government benefit" it seeks is continued "Medicare and Medicaid participation" and making sales of its drugs to Medicare beneficiaries. Pls. Br. at 58. Novo appears to recognize that this is not a benefit the government is required to provide—and rightly so. *Id.* As

detailed further in the next section, *see infra* at 54-56, Novo has no vested right to conduct business with the government at all, and no vested property right to continue participating in Medicare. *Chamber*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). What then is the vested property interest that Congress supposedly leveraged in exchange for that benefit? In Novo's telling, it is the *procedural* right to ensure that the government fairly sets the price for *those very sales to Medicare*, to ensure that they are not unfairly low. *See* Pls. Br. at 45-47 (arguing that "the IRA includes no procedures to protect against arbitrary or confiscatory pricing" and lacks a "guarantee that CMS will set a price that will allow Novo to obtain any return on its investment"). This argument is circular. Novo is not claiming that there are free-standing commercial sales that the government is seeking to regulate in exchange for some benefit. *See id.* Rather, the lack of process they claim as a violation of their rights concerns the *very same Medicare sales* that Novo is seeking as a benefit.

Not surprisingly, Novo identifies no case that bootstrapped an unconstitutional conditions theory in this manner. *See id.* Indeed, Novo's argument amounts to nothing more than the idea that the government denies manufacturers a constitutional right by not structuring the benefit in the way that manufacturers like. But the Supreme Court has "never held that the [government] must grant a benefit . . . to a person who wishes to exercise a constitutional right." *Regan v. Tax'n with Representation of Washington*, 461 U.S. 540, 545 (1983); *see also J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). Just as a

government contractor cannot claim that the denial of a contract improperly infringed on his procedural rights to negotiate that contract, so too the government cannot violate the unconstitutional conditions doctrine by offering allegedly inadequate procedures for negotiating the price that the government will pay for manufacturers' drugs.

2. Rather than engage with this analytical problem, Novo claims that the Negotiation Program does not satisfy the "nexus and rough proportionality" test articulated by the Supreme Court in *Koontz*. Pls. Br. at 58. But, apart from failing to cure the intractable flaw in Novo's theory, this argument runs aground on established precedent.

The nexus-and-rough-proportionality test comes not from a due process lineage but rather from a pair of land-use cases, *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834-37 (1987) and *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994). The Supreme Court has explicitly rejected extending that test beyond "the special context of [] land-use decisions conditioning approval of development on the dedication of property to public use," *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702 (1999). Indeed, the *Koontz* case Novo itself cites makes clear that the *Nollan* and *Dolan* test is reserved for the "'special application' of . . . land-use permits." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (discussing the doctrine); *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting the "special context of land-use exactions"). That is for good reason. The "realities of the permitting process" render applicants "especially vulnerable" to the government's demands "because the government often has broad discretion to deny a permit that is worth far more than property it would like to take." *Koontz*, 570 U.S. at 604-05. Evaluating whether a land-use exaction is "proportional[]" to the governmental benefit thus ensures that the condition is part

of a voluntary exchange. *Id.*; *see also Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (explaining this framework).

By contrast, no such proxy tests are necessary or appropriate when Congress merely sets the terms on which the government will do business—business to which the party has no free-standing entitlement and which it can freely decline. Courts do not, for example, superintend government contracts to ensure that they are voluntary and provide contractors sufficient compensation or benefit to avoid a Fifth Amendment taking. *See, e.g.*, *St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1385 (Fed. Cir. 2008) ("In general, takings claims do not arise under a government contract because . . . the government is acting in its proprietary rather than its sovereign capacity" and any right to compensation has "been voluntarily created" (citations omitted)). Novo may be unhappy that Congress created the Negotiation Program as a condition of future Medicare and Medicaid participation. But Novo's dissatisfaction does not mean that the condition is improper in a constitutional sense.

* * *

Simply put, Novo cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber*, 2023 WL 6378423, at *11. And because "there is no legal compulsion to" participate, "there can be no" Fifth Amendment violation. *Garelick*, 987 F.2d at 916.

IV. NOVO'S DUE PROCESS CHALLENGE FAILS ON ITS OWN TERMS

Even setting aside the voluntary nature of the Negotiation Program—and the settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps—Novo's due process claim still fails even as articulated.

The Due Process Clause protects against deprivation "of life, liberty, or property, without due process of law," U.S. Const. amend. V. But the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). A protected property interest arises where an individual has "a legitimate claim of entitlement" to a particular benefit, not merely a "unilateral expectation" or "abstract need or desire" for it. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). These property interests are "not created by the Constitution, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538 (1985). As a result, "a party cannot possess a property interest in the receipt of a benefit when the state's decision to award or withhold the benefit is wholly discretionary." *Med Corp., Inc. v. City of Lima,* 296 F.3d 404, 409 (6th Cir. 2002). Rather, "to establish a constitutionally protected property interest," plaintiff "'must point to some policy, law, or mutually explicit understanding that both confers the benefits and limits the discretion of the [government] to rescind'" it. *Keego Harbor*, 397 F.3d at 435 (quoting *Med Corp.*, 296 F.3d at 410).

Novo has not—and cannot—do so. Although manufacturers have a protected property interest in their physical drugs, the IRA does not infringe on that interest because it only regulates how much Medicare will reimburse participating

manufacturers—but does not require those manufacturers to make any sales in the first instance. *See, e.g.*, 42 U.S.C. § 1320f-2(a)(1), (3) (agreements only regulate the price at which drugs are sold, not whether sales are made); 42 U.S.C. § 1320f-6(a) (penalties apply for failure to "provide access to a *price*" (emphasis added)). And, contrary to Novo's claims, manufacturers do not have an inherent entitlement—and therefore do not have a property interest—in selling their drugs to Medicare at any particular price. *Contra* Pls. Br. at 44 (claiming that Novo has a "right[] to sell its products at market-based prices" and that "Novo has relied on the promise of future sales" in making business decisions (quoting *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936)).

As courts have repeatedly explained, "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia v. People of State of New York*, 291 U.S. 502, 527-28 (1934); *see also Chamber*, 2023 WL 6378423, at *11. And that is even more obviously true when the business in question operates in a heavily regulated space or requires an outlay of taxpayer funds. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 1006-07; *see also Minn. Ass'n*, 742 F.2d at 446-47 (hospitals that "serve medical assistance recipients have no constitutional right to be free from [government] controls on the rates they charge [patients] who do not receive medical assistance"). Thus, as the *Chamber* court correctly recognized, no one is entitled to conduct business with the government in the first instance. *Chamber*, 2023 WL 6378423, at *11; *see also Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) ("[N]o one has a 'right' to sell to the government that which the government does not wish to buy."); *Perkins*, 310 U.S. at 127 (government has authority to "determine those with

whom it will deal"); *J.H. Rutter*, 706 F.2d at 712 (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). By extension, as courts have repeatedly emphasized, no one has a property interest in future Medicare sales. *See, e.g.*, *Shah*, 920 F.3d at 998 ("[P]articipation in the federal Medicare reimbursement program is not a property interest."); *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013) ("[P]roviders do not have a property interest in a particular reimbursement rate."); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner").

Indeed, crediting Novo's claim that manufacturers have a protected property interest in future Medicare sales would mean that the manufacturers have a *constitutional* right to dictate the government's expenditures. *See* Pls. Br. at 44. But it is well established that "Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds." *NFIB*, 567 U.S. at 579; *see also Sabri*, 541 U.S. at 608. Not surprisingly, then, courts have explicitly rejected the core premise of Novo's theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr.*, 934 F.2d at 721. Just as a defense contractor could not build an aircraft carrier and force an unwilling Pentagon to buy it (at any price), so too manufacturers cannot force their drugs onto the government at unilaterally dictated rates.

In the absence of a protected property interest, Novo's due process claim collapses. *See, e.g.*, *Keego Harbor*, 397 F.3d at 434 ("In order to assert a valid due process claim . . . a plaintiff must establish that the interest asserted is a liberty or property

interest."). For that reason, there is no need for the Court to address the due-process balancing test set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976). Pls. Br. at 45. Simply put, the IRA cannot deprive Novo of due process of law in setting the price for Medicare sales when Novo has no protected property interest in those sales to begin with. *See, e.g.*, *Roth,* 408 U.S. at 578 (untenured professor, whose appointment was for only one year, did not possess a protected property interest in his continued employment, and university was therefore not required "to give him a hearing when they declined to renew his contract of employment").

V. NOVO'S FIRST AMENDMENT CHALLENGE FAILS BECAUSE THE NEGOTIATION PROGRAM DOES NOT COMPEL MANUFACTURERS TO SPEAK

Novo's First Amendment claim similarly lacks merit. That challenge rests entirely on Novo's unsupported assertions that the agreements manufacturers sign with CMS constitute improperly "compelled" "speech," and thus violate the First Amendment. Pls. Br. at 48. But this is not true.

1. As an initial matter, reaching an agreement with CMS is not speech, nor is it expressive conduct. Any "speech" that may ordinarily be implicated in the execution of a commercial contract "is plainly incidental to the . . . regulation of conduct" that the contract governs. *FAIR*, 547 U.S. at 62. And the regulation of conduct "has never been deemed an abridgment of freedom of speech . . . merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). Medicare routinely uses agreements that health care providers and other entities may sign to memorialize their voluntary acceptance of the terms for participation

in the program; those agreements do not signify providers' endorsement of, for example, the general fairness of the Medicare rate-setting process. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c). The agreements memorializing manufacturers' acceptance of the terms for participation in the Negotiation Program are no different.

A manufacturer that chooses to sign an agreement with CMS undertakes a voluntary obligation to negotiate prices and, ultimately, to provide Medicare beneficiaries with access to the negotiated prices for the selected drugs that the manufacturer sells. *See* Revised Guidance at 118-20; *see also* CMS, Medicare Drug Price Negotiation Program Agreement, https://perma.cc/6VG4-KKF6 (Template Agreement). This does not implicate the First Amendment any more than "typical price regulation," which "would simply regulate the amount [of money] that a [manufacturer] could collect." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). Indeed, courts have confirmed again and again that "ordinary price regulation does not implicate constitutionally protected speech," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019) (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Campbell v. Robb*, 162 F. App'x 460, 468 (6th Cir. 2006) (recognizing "the general principle that government retains its full power to regulate commercial transactions directly, despite elements of speech and association inherent in such transactions"). In the same way, because the requirement that a participating manufacturer sign an agreement "is imposed 'for reasons unrelated to the communication of ideas,'" that requirement does "not implicate the First Amendment." *Nicopure*, 944 F.3d at 291 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)); *see also Expressions Hair Design*, 581 U.S. at 47 (where a "law's effect on

speech would be only incidental to its primary effect on conduct," the law is not a regulation of speech subject to First Amendment scrutiny).

The fact that the negotiation agreement "is not inherently expressive," *FAIR*, 547 U.S. at 64, is "underscored by [the agreement's] bearing only on product price," *Nicopure*, 944 F.3d at 292. The terms of the agreement explicitly state what is already apparent: a manufacturer's signature constitutes neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. *See* Template Agreement at 4 (explaining that, by "signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views"). Lest there be any doubt, the agreement affirms that the use "of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.* In other words, the agreement uses statutory terms merely as a way of clarifying the parties' respective obligations.

This commercial arrangement is nothing like regulations requiring expressive conduct, which is what was at issue in the cases Novo cites. *See, e.g.*, *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2464 (2018) (holding that requiring public employees to pay union fees violated their free speech rights); *303 Creative LLC v. Elenis*, 600 U.S. 570, 579, 593-94 (2023) (holding that state could not require website designer to design websites expressing messages with which she disagrees where the parties had stipulated that those "websites will be expressive in nature" (citation omitted)); *see generally* Pls. Br. at 48-49. The agreement to negotiate does not require

manufacturers "to utter or distribute speech bearing a particular message," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994), or to say anything about any agreed-upon prices. Nor does the agreement restrict manufacturers' ability to say whatever they wish about the Negotiation Program or to criticize CMS or the IRA. *Contra* Pls. Br. at 50-51.

A manufacturer may, of course, have numerous reasons for signing or not signing an agreement with CMS, and some of those reasons may pertain to views that it holds or wants to communicate to others. But a manufacturer's views regarding the IRA or negotiated prices "do[] not convert all regulation that affects access to [selected drugs] into speech restrictions subject to First Amendment scrutiny." *Nicopure*, 944 F.3d at 291; *see generally City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) ("It is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment."). Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance to the flag . . . or forcing a Jehovah's Witness to display a particular motto on his license plate . . . and it trivializes the freedom protected in [those circumstances] to suggest that it is." *FAIR*, 547 U.S. at 48 (citing *W. Va. Bd. of Educ. v. Barnette,* 319 U.S. 624 (1943), and *Wooley v. Maynard,* 430 U.S. 705 (1977)).

2. Novo's First Amendment arguments are all the more inapt given that the Negotiation Program is voluntary, and thus does not compel any manufacturer to sign an agreement—or to do anything at all. *See supra* at 35-41; *see also Chamber*, 2023 WL 6378423, at *11. The First Amendment does not prohibit the government from giving

a company the option to sign an agreement governing the terms of a program in which the company chooses to participate. *See, e.g.*, *FAIR*, 547 U.S. at 59 (noting that "Congress is free to attach reasonable and unambiguous conditions to federal" funds without triggering First Amendment scrutiny (quoting *Grove City College v. Bell*, 465 U.S. 555, 575-76 (1984)). Just as manufacturers are not forced to sell drugs to Medicare, manufacturers are not forced to sign agreements to negotiate the prices of those drugs.

Indeed, the Supreme Court has long upheld conditions on speech that pertain to the nature of a government program. As the Court has explained, if a program arises under the Spending Clause, Congress is free to attach "conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize." *Agency for Int'l Dev.*, 570 U.S. at 214; *see, e.g.*, *United States v. Am. Lib. Ass'n*, 539 U.S. 194, 212 (2003) (plurality opinion) (rejecting a claim by public libraries that conditioning funds for Internet access on the libraries' installing filtering software violated their First Amendment rights, explaining that "[t]o the extent that libraries wish to offer unfiltered access, they are free to do so without federal assistance"); *Regan*, 461 U.S. at 546 (dismissing "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State" (citation omitted)).

Here, the supposed condition about which Novo complains is the signing of an agreement to negotiate and, ultimately, a pricing agreement. These voluntary agreements are the core mechanisms by which negotiations will proceed, and the source of the enforceable obligation for manufacturers to provide selected drugs at negotiated prices. *See* Revised Guidance at 118-20. In this way, these agreements "define the [Negotiation] program and" do not "reach outside it." *Agency for Int'l Dev.*, 570 U.S. at

217. Accordingly, even if the agreements were expressive—which they are not—they would be an appropriate way "to ensure that the limits of the federal program are observed" and that Medicare funds are "spent for the purposes for which they were authorized." *Rust v. Sullivan*, 500 U.S. 173, 193, 196 (1991).

VI. NOVO'S SEPARATION OF POWERS CLAIM FAILS

Finally, Novo argues that the statute violates the nondelegation doctrine because it lacks an "intelligible principle." Pls.' Br. at 40-42 (cleaned up). Perhaps recognizing the headwinds faced by such a claim, Novo seeks to fortify its arguments by drawing contrasts between the Negotiation Program and a series of unrelated regulatory regimes. *Id.* at 51-53. But, no matter how they come garbed, Novo's arguments fail to establish a nondelegation claim—an attack that has not prevailed at the Supreme Court in nearly a century. There is no legal basis for this Court to deviate from that unbroken line of precedent.

1. Under what Plaintiffs concede are "the Supreme Court's modern nondelegation doctrine cases," *id.*, delegations by Congress to the Executive Branch are constitutional "[s]o long as Congress 'shall lay down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform.'" *Mistretta v. United States*, 488 U.S. 361, 372 (1989) (quoting *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928)). Under this standard, it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946).

This framework is "not demanding." *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality op.). Congress has delegated authority "from the beginning of the government," *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 442 (5th Cir. 2020) (quoting *United States v. Grimaud*, 220 U.S. 506, 517 (1911)), and "[o]n only two occasions has the Court invalidated legislation based on the nondelegation doctrine, and both occurred in 1935." *United States v. Cooper*, 750 F.3d 263, 268 (3d Cir. 2014). One of those statutory provisions "provided literally no guidance for the exercise of discretion," and the other "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)). By contrast, in the almost 90 years since, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Mistretta*, 488 U.S. at 373, and "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,'" *Am. Trucking*, 531 U.S. at 474-75 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)).

Applying those principles, the Supreme Court has upheld nearly every delegation it has confronted, including delegations to various agencies to regulate in the "public interest," *National Broadcasting Co. v. United States*, 319 U.S. 190, 216 (1943), *New York Central Securities Corp. v. United States*, 287 U.S. 12, 24 (1932)); to set "fair and equitable" prices and "just and reasonable" rates, *Yakus v. United States*, 321 U.S. 414, 422, 427 (1944), *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944)); and to issue whatever air quality standards are "requisite to protect the public health," *Whitman v. American*

Trucking Assns., Inc., 531 U.S. 457, 472 (2001). Ultimately, the Supreme Court's non-delegation "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." *Mistretta*, 488 U.S. at 472. As the Court has confirmed, the Constitution allows "Congress to obtain the assistance of its coordinate Branches," and to "confer substantial discretion on executive agencies to implement and enforce the laws." *Gundy*, 139 S. Ct. at 2123 (plurality op.)).

The IRA fits comfortably within these precedents. At the outset, Congress itself made many of the key "legislative determination[s]" in creating the Negotiation Program, "which has the effect of constricting the [agency's] discretion to a narrow and defined category." *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009). For example, Congress established multiple mathematical formulae for calculating a ceiling price. *See* 42 U.S.C. § 1320f-3(c). Congress then (1) delegated to CMS the task of representing the government in negotiations, *id.* § 1320f-3(a), (2) directed it to "aim[] to achieve the lowest maximum fair price for each selected drug" for which it is able to persuade manufacturers to sign an agreement, *id.* § 1320f-3(b)(1), and (3) specified detailed criteria that CMS "shall consider" in "determining the offers and counteroffers" during the negotiation, up to the congressionally specified ceiling price, using data "submitted by the manufacturer":

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

> (B) Current unit costs of production and distribution of the drug.
>
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
>
> (D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under [the Food Drug and Cosmetic Act].
>
> (E) Market data and revenue and sales volume data for the drug in the United States.

Id. § 1320f-3(e)(1). Congress also mandated consideration of "evidence" about "therapeutic alternatives to such drug":

> (A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.
>
> (B) Prescribing information approved by the [FDA] for such drug and therapeutic alternatives to such drug.
>
> (C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.
>
> (D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Id. § 1320f-3(e)(2).[11] That was more than enough. In fact, Congress used far more detail here than in dozens of statutes that have been upheld in the face of nondelegation

[11] Congress also specified that, "[i]n using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill

challenges in the past century. *See, e.g.*, *Am. Trucking*, 531 U.S. at 472 ("protect the public health"); *Nat'l Broad.*, 319 U.S. at 225-26 ("public interest, convenience, or necessity"). Especially in the context of a delegation governing the negotiation of individual contracts—a traditional Executive Branch function—no further detail was necessary. *See, e.g.*, *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (recognizing "the traditional principle of [Congress] leaving purchases necessary to the operation of our Government to administration by the executive branch of Government, with adequate range of discretion free from vexatious and dilatory restraints at the suits of prospective or potential sellers").

Novo seems most concerned with the lack of a specific and binding formula for CMS to use in calculating an offer price (other than the statutory ceiling price, *see* 42 U.S.C. § 1320f-3(c)). *See* Pls.' Br. at 41 (asserting, incorrectly, that "there is no legal standard to govern CMS's price-setting decision"). It is difficult to imagine how Congress could have perfected such a formula, given the wide variety of drugs that will be covered by the Negotiation Program. In any event, no precedent "stand[s] for the proposition that delegations lacking some sort of Congressional formula lack sufficient guidance." *Consumers' Rsch. v. FCC*, 67 F.4th 773, 790 (6th Cir. 2023).

2. Unable to overcome these precedents directly, Novo attempts to get around them by claiming that the delegation here "is made worse by Congress's decision to withdraw judicial review of CMS's price-setting decisions." Pls. Br. at 42 (citing 42 U.S.C. § 1320f-7). But this is merely a policy complaint in search of a legal theory.

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individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." 42 U.S.C. § 1320f-3(e)(2)(D).

As a threshold matter, preclusion of review has no logical connection to the operative question under the nondelegation doctrine: whether Congress provided an intelligible principle to guide agency discretion. And although Plaintiffs cite out-of-circuit dicta (at 42) for the theory that the *availability* of "judicial review is a factor weighing in favor of *upholding* a statute against a nondelegation challenge," *United States v. Garfinkel*, 29 F.3d 451, 458-59 (8th Cir. 1994) (emphasis added), they cite nothing for the idea that *preclusion* of review creates a nondelegation problem, and Defendants are aware of no such case. At least one holds the opposite. *See United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992) ("[T]he EAA's preclusion of judicial review does not violate the nondelegation doctrine."). That is unsurprising: the nondelegation doctrine is about the power that Congress has delegated to the Executive Branch, on the front end—not whether the exercise of that power is subject to otherwise-unrelated constraints, on the back end.

Indeed, Novo's theory that preclusion of review creates a delegation problem is inconsistent with (yet another) line of settled precedent—which holds that, at least within outer bounds not relevant here,[12] Congress's "control over the jurisdiction of the federal courts is plenary." *Patchak v. Zinke*, 138 S. Ct. 897, 906 (2018) (citation omitted). Because Congress alone "possess[es] the sole power of creating the tribunals (inferior to the Supreme Court)," it also has the exclusive power "of withholding

[12] For example, the Supreme Court has suggested that it would raise a "serious constitutional question" if a preclusion provision were read "to deny a judicial forum for a colorable constitutional claim." *Webster v. Doe*, 486 U.S. 592, 603 (1989). The government has not argued here (or in any of the other cases challenging the Negotiation Program) that 42 U.S.C. § 1320f-7 forecloses judicial review of any constitutional claims that plaintiffs have brought.

jurisdiction from them in the exact degrees and character which to Congress may seem proper for the public good." *Palmore v. United States*, 411 U.S. 389, 400-01 (1973) (quoting *Cary v. Curtis*, 44 U.S. 236, 245 (1845)); *accord Kontrick v. Ryan*, 540 U.S. 443, 452 (2004) ("Only Congress may determine a lower federal court's subject-matter jurisdiction." (citing U.S. Const. art. III, § 1)). Ultimately, when Congress limits federal jurisdiction, "it exercises a valid legislative power no less than when it lays taxes, coins money, declares war, or invokes any other power that the Constitution grants it." *Patchak*, 138 S. Ct. at 906. And "what the Congress gives, the Congress may take away." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017).

Novo calls congressional preclusion of judicial review over certain agency determinations "significant and unusual." Pls.' Br. at 42 (quoting *Free Enter. Fund v. Public Co. Acct. Oversight Bd.*, 561 U.S. 477, 506 (2010)).[13] In fact, it is neither. Even the Administrative Procedure Act (APA) itself—which creates the fundamental framework for judicial review of agency action—has an explicit textual exception for the common situations in which other "statutes preclude judicial review," or when "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). Courts have applied these sorts of preclusion provisions for decades, without ever suggesting that they create (or contribute to) a nondelegation problem.[14] Even focusing on Medicare alone, Congress

[13] Novo cites to *Free Enterprise Fund*, but that case is about the Appointments Clause and the related Article II limitations on Congress's ability to restrict the President's removal power. Novo does not bring any appointment or removal claims in this case, so cases like *Free Enterprise Fund* have little relevance.

[14] *See, e.g.*, *Webster*, 486 U.S. at 603 (no judicial review of certain agency actions under the APA); *Heckler v. Chaney*, 470 U.S. 821 (1985) (same); *S. Ry. Co. v. Seaboard*

has enacted dozens of similar provisions, *see, e.g.*, 42 U.S.C. §§ 1395 *et seq.* (using the phrase "no administrative or judicial review" dozens of times), which courts have applied with little controversy. *See, e.g.*, *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022); *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019); *Knapp*, 875 F.3d at 1129; *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 532 (5th Cir. 2012); *see also supra* at 16-17 (cataloging cases).

The IRA raises no nondelegation problem.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion on all claims.

Allied Milling Corp., 442 U.S. 444, 454 (1979) (same, under the Interstate Commerce Act); *Briscoe v. Bell*, 432 U.S. 404 (1977) (same, under the Voting Rights Act); *Schilling v. Rogers*, 363 U.S. 666 (1960) (same, under the Trading with the Enemy Act); *Arizona*, 40 F.4th at 389 (same, under the APA).

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